

**Department of Planning and Budget  
2026 General Assembly Session  
State Fiscal Impact Statement**

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**ORIGINAL**

**Bill Number:** SB374S1

**Patron:** Boysko

**Bill Title:** Newborn screening requirements

**Bill Summary:** This legislation, as amended in the nature of a substitute, require the Virginia Department of Health (VDH) conduct an evaluation to determine whether Gaucher disease should be included in the Commonwealth's newborn screening panel and if applicable to commence the rulemaking process to add such disorder to the testing required under § 32.1-65 of the Code of Virginia in the same manner as is required for any disorder included on the Recommended Uniform Screening Panel

**Budget Amendment Necessary:** Yes

**Items Impacted:** 68 and 277

**Explanation:** VDH would require additional general fund appropriation and may require nongeneral fund appropriation attributable to item 277. The Department of General Services (DGS) Division of Consolidated Laboratory Services (DCLS) and may require additional nongeneral fund appropriation attributable to Item 68 (DGS).

**Fiscal Summary:** VDH's Virginias Newborn Screening Program (VNBSP) currently operates through fee revenue received for providing newborn screening services. Current fee revenue is collected by DGS-DCLS in a special fund and is used to support program costs, including personnel, at VDH. VDH estimates that it would take one year to do a comprehensive evaluation to determine if Gaucher disease should be included in the newborn screening panel. While DCLS has the ability to increase fees for each disorder added to the newborn screening panel, it is unknown if Gaucher disease would ultimately be added to the newborn screening panel. Therefore, it is unknown if there is a need for a fee increase. As a result, VDH would need general fund appropriation in the first year for the evaluation. VDH and DCLS may need additional nongeneral fund appropriation in subsequent years for any additional revenue received.

**General Fund Expenditure Impact:**

<u>Agency</u>	<u>FY2026</u>	<u>FY2027</u>	<u>FY2028</u>	<u>FY2029</u>	<u>FY2030</u>	<u>FY2031</u>
VDH (601)	-	\$300,000 - \$500,000	-	-	-	-
DGS-DCLS (194)	-	-	-	-	-	-
<b>TOTAL</b>	-	\$300,00 - \$500,000	-	-	-	-

**Nongeneral Fund Expenditure Impact:**

<u>Agency</u>	<u>FY2026</u>	<u>FY2027</u>	<u>FY2028</u>	<u>FY2029</u>	<u>FY2030</u>	<u>FY2031</u>
VDH (601)	-	-	Indeterminate	Indeterminate	Indeterminate	Indeterminate
DGS-DCLS (194)	-	-	Indeterminate	Indeterminate	Indeterminate	Indeterminate
<b>TOTAL</b>	-	-	Indeterminate	Indeterminate	Indeterminate	Indeterminate

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**Revenue Impact:**

<u>Agency</u>	<u>FY2026</u>	<u>FY2027</u>	<u>FY2028</u>	<u>FY2029</u>	<u>FY2030</u>	<u>FY2031</u>
VDH (601)	-	-	Indeterminate	Indeterminate	Indeterminate	Indeterminate
DGS-DCLS (194)	-	-	Indeterminate	Indeterminate	Indeterminate	Indeterminate
<b>TOTAL</b>	-	-	Indeterminate	Indeterminate	Indeterminate	Indeterminate

**Fiscal Analysis:** The provisions of this legislation, as amended, require VDH to conduct an evaluation to determine whether Gaucher disease should be included in the Commonwealth's newborn screening panel. Gaucher disease is currently not on the federal Recommended Uniform Screening Panel (RUSP). VDH's Office of Family Health Services (OFHS), which oversees the VN BSP, has not historically reviewed non-RUSP disorders for inclusion on the newborn screening panel. The federal entity that previously conducted the rigorous disorder review, the Advisory Committee for Heritable Disorders in Newborns and Children, was terminated by the U.S. Department of Health and Human Services (HHS) in April 2025. This means that OFHS would be responsible for identifying and synthesizing clinical research on the disorder, screening, diagnostics, and treatment along with convening a workgroup, writing a report, and more.

VDH does not have sufficient expertise to conduct the advanced scientific research and clinical review necessary for non-RUSP disorders and would require contracting with specialty clinical consultants. Clinical specialists will provide subject matter expertise on disorder diagnosis, care management, treatment requirements in addition to evaluating documentation and compiled resources. Gaucher disease has been added to the newborn screening panels in the following states: Illinois, Missouri, Tennessee, New Mexico, New York, and Maryland. It is assumed that the consultant can leverage existing programs and evaluations performed in other states during their evaluation. Based on independent research, estimated costs to evaluate a disorder for possible inclusion on a newborn screening panel range from \$330,558 to \$508,481.

Any increase in workload to compile the results of the evaluation for inclusion in a report per §32.1-65, Code of Virginia, can be handled within existing resources. VDH currently submits a status report to the General Assembly on the screening program annually.

The Department of General Services (DGS) Division of Consolidated Laboratory Services (DCLS) would partner with VDH to conduct an evaluation in accordance with the amendment, as described. DCLS anticipates that its assistance to VDH with the evaluation can be completed using existing resources.

The current cost to screen one panel is \$138. DCLS would increase fees should Gaucher disease be added to the newborn screening panel. The addition of Gaucher disease is projected to require a further \$1.50 per kit (the current collection kit price is \$138). Using an annual birth rate of 95,000 based on recent vital records data, the fee increase would generate an additional \$142,500.

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The fiscal impact on the Department of Medical Assistance Services should Gaucher disorder be added to the newborn screening panel cannot be determined as the agency could experience an increase in follow-up screenings and additional treatment costs.

**Other:** None